

JUL - 7 2005

K05D032 pg. 1 of 3

FLUENCY® Plus Tracheobronchial Stent Graft
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug, and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

General Information:

Submitter Name: Bard Peripheral Vascular, Inc.
Address: 1625 W. Third Street
P.O. BOX 1740
Tempe, AZ 85280-1740

Telephone Number: (480) 894-9515
Fax Number: (480) 449-2546

Contact Person: Dennis Salzmnn, Ph.D.
Regulatory Affairs Technical Manager

Device Information:

Device Trade Name: **FLUENCY® Plus Tracheobronchial Stent Graft**
Common/Usual Name: Tracheal Prosthesis
Classification: Class II with Special Controls

The special controls for this device are compliant with FDA *Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses*. April 28, 1998.

Classification Panel: General & Plastic Surgery

Predicate Device:

FLUENCY® Tracheobronchial Stent Graft (K031041, cleared June 19, 2003)

Summary of Change:

The design modifications to the FLUENCY® Tracheobronchial Stent Graft are modification of the inner catheter tip, and modification to the outer catheter material and configuration. These changes result in a subject device that has a reduced deployment force, reduced risk of tip entanglement during withdrawal of the delivery system, allows

for more precise stent graft placement during deployment, and provides more delivery system length options for physicians. All other aspects of the subject device remain the same as the predicate device.

Device Description:

The FLUENCY® Plus Tracheobronchial Stent Graft includes a self-expanding Nitinol stent encapsulated with carbon-impregnated ePTFE pre-loaded on a flexible "pull-back" delivery system. It is a single use prosthetic device designed to maintain the patency of the tracheobronchial tree in patients with tracheobronchial strictures. Highly radiopaque tantalum markers on the stent graft ends facilitate stent graft placement. The FLUENCY® Plus Tracheobronchial Stent Graft is available in various lengths and diameters. It is preloaded into various size delivery catheters, depending on the size of the stent graft and is available in various delivery system lengths.

Intended Use of Device:

The FLUENCY® Plus Tracheobronchial Stent Graft is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

Technological Comparison to Predicate Device:

The technological characteristics of FLUENCY® Plus Tracheobronchial Stent Graft are substantially equivalent to those of the predicate FLUENCY® Tracheobronchial Stent Graft in terms of intended use, application, user population, basic design, performance, labeling, packaging, and sterilization method.

Non-Clinical Performance Data:

Design verification and validation of the modified device was done with conformance to or evaluated based on the following FDA guidance:

Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses. April 28, 1998.

All test results confirm the modified device to be substantially equivalent to the predicate device.

Conclusions:

The FLUENCY® Plus Tracheobronchial Stent Graft met all the predetermined performance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The FLUENCY® Plus Tracheobronchial Stent Graft is substantially equivalent to the legally marketed predicate device, the FLUENCY® Tracheobronchial Stent Graft.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 16 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bard Peripheral Vascular, Inc.
% Mr. Joshua Smale
Regulatory Affairs Specialist
1625 West 3rd Street
P.O. Box 1740
Tempe, Arizona 85280

Re: K050832

Trade/Device Name: FLUENCY[®] Plus Tracheobronchial Stent Graft
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: June 6, 2005
Received: June 7, 2005

Dear Mr. Smale:

This letter corrects our substantially equivalent letter of July 7, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 - Mr. Joshua Smale

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K050832

Device Name: FLUENCY® Plus Tracheobronchial Stent Graft

Indications for Use:

The FLUENCY® Plus Tracheobronchial Stent Graft is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K050832